C. Remarks

The claims are 12, 15, 16, 19 and 20, with claim 12 being the sole independent claim. Claim 12 has been amended to make clear that the composition disintegrates within 1 to 60 seconds of being placed in contact with fluid. Support for this amendment may be found, *inter alia*, in original claim 2. All claims have been amended to correct minor informalities. Applicants submit that no new matter has been added by way of these amendments. It should be noted that in the Amendment filed on January 3, 2007, claims 13 and 18 were cancelled without prejudice or disclaimer; however, in the listing of the claims, erroneous claim language was inadvertently included next to claims 13 and 18. Those claims are now properly listed as "cancelled" in the present listing of the claims section. Reconsideration of the present claims is respectfully requested.

Claims 12, 13, 15, 16 and 18-20 stand rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. In view of Applicants' amendment of claim 12 clarifying that the composition disintegrates within 1 to 60 seconds of being placed in contact with fluid as suggested by the Examiner, Applicants submit that the §112 rejection has been overcome and should be withdrawn.

Claims 12, 13, 15, 16 and 18-20 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Devereaux* (U.S. Patent No. 6,267,969). Applicants respectfully traverse this rejection.

Devereaux is directed to a reagent composition comprising an assay reagent incorporated within a porous material, and the porous material is then coated or encapsulated with a carrier matrix. The carrier matrix is typically a gelatin, such as fish gelatin. See *Devereaux*, col. 2, line 42 to col. 3, line 11. However, *Devereaux* does not teach or suggest a non-hydrolyzed, non-gelling fish gelatin as required by the present claims. The Examiner asserts that *Devereaux* does not "indicate the type of the gelatin and the silence would mean that all forms of the fish gelatin is contemplated for use." Office Action, page 6. Applicants respectfully disagree with the Examiner's position. *Devereaux* in fact, discloses the use of a *gelling* fish gelatin by disclosing that "Assay reagents are easily mixed with gelatin solutions, and the cooled *gelatin forms a gelled mass* which is readily moldable." *Devereaux*, col. 9, lines 12-10 (emphasis added). Hence, *Devereaux* actually teaches away from the claimed invention which requires a non-gelling fish gelatin.

Furthermore, the Examiner asserts that "any of the fish gelatin could be used with the expectation of the *same* results from each of the types of the fish gelatin." Office Action, page 6 (emphasis added). This is simply not true. In fact, the non-gelling variety of fish gelatin has comparatively lower proline and hydroxyproline contents as compared to gelling fish gelatin. Given that it has been known that these contents are associated with cross-linking properties and gelling ability (*id.* at page 8), it was surprising that the non-gelling form of fish gelatin could be advantageously used in rapid disintegrating dosage forms. *Id.* at page 5. Accordingly, a person skilled in the art reading the disclosure of *Devereaux* would not be motivated to replace the gelling fish gelatin of *Devereaux* with the non-hydrolyzed, non-gelling fish gelatin of the claimed invention (which would have been expected to have comparatively lower cross-linking abilities).

In addition, the Examiner previously noted that "Applicant has not provided factual evidence that the recited fish gelatin provides unexpected results over the other types of fish gelatin." Office Action dated October 19, 2006, page 5. Applicants again respectfully disagree with the Examiner and point to Example 5 of the present specification entitled "Testing of 'Gelling' Fish Gelatin". In Example 5, a formulation containing gelling fish gelatin was prepared and evaluated for disintegration time and mouth feel. Specification, page 23. It was found that the mouthfeel of the formulation was "gummy" in nature and overall *unsatisfactory*. *Id.* at page 24 (emphasis added). Given this, one of ordinary skill in the art would not incorporate a gelling fish gelatin (as disclosed in *Devereaux*) in the composition of the present invention.

Finally, and as previously argued, *Devereaux* is non-analogous art as it is directed to a wash-away coating that leaves behind one or more active ingredients bound to an insoluble structure as embodied in all the examples. Simply put, one of ordinary skill in the art would not turn to *Devereaux* for guidance in achieving a free standing structural matrix such as is presently claimed, wherein the active ingredient is contained within the carrier matrix and whereby, upon use, the carrier matrix essentially dissolves, leaving nothing analogous to the porous material of *Devereaux* behind.

In sum, *Devereaux* does not render the present invention obvious. *Devereaux* fails to disclose or suggest at least certain key features of the present invention, namely the use of a non-hydrolyzed, non-gelling fish gelatin carrier in a pharmaceutical composition that disintegrates within 1 to 60 seconds of being placed in contact with fluid. Accordingly, Applicants respectfully request withdrawal of the §103 rejection.

In view of the foregoing amendments and remarks, Applicants respectfully request favorable reconsideration and allowance of the claims in the present application. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicants' undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

Elizabeth F. Holowacz
Attorney for Applicants
Registration No.: 42,667

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200

FCHS_WS 2219716_1